PUBLISHED

UNITED STATES COURT OF APPEALS

FOR THE FOURTH CIRCUIT

C.B. FLEET COMPANY, INCORPORATED, A Virginia corporation, Plaintiff-Appellant,

v.

No. 96-2606

SMITHKLINE BEECHAM CONSUMER HEALTHCARE, L.P., A Delaware limited partnership, Defendant-Appellee.

Appeal from the United States District Court for the Western District of Virginia, at Lynchburg. James C. Turk, District Judge. (CA-95-48)

Argued: June 5, 1997

Decided: December 10, 1997

Before WILKINS and MICHAEL, Circuit Judges, and PHILLIPS, Senior Circuit Judge.

Affirmed by published opinion. Senior Judge Phillips wrote the opinion, in which Judge Wilkins and Judge Michael joined.

COUNSEL

ARGUED: Rodney F. Page, ARENT, FOX, KINTNER, PLOTKIN & KAHN, Washington, D.C., for Appellant. Kenneth Allen Plevan, SKADDEN, ARPS, SLATE, MEAGHER & FLOM, L.L.P., New

York, New York, for Appellee. **ON BRIEF:** Peter S. Reichertz, ARENT, FOX, KINTNER, PLOTKIN & KAHN, Washington, D.C., for Appellant. Bruce J. Goldner, SKADDEN, ARPS, SLATE, MEAGHER & FLOM, L.L.P., New York, New York; William B. Poff, Sara B. Winn, WOODS, ROGERS & HAZLEGROVE, P.L.C., Roanoke, Virginia, for Appellee.

OPINION

PHILLIPS, Senior Circuit Judge:

This is an appeal by C.B. Fleet Company, Inc. (Fleet), a manufacturer of feminine hygiene products, from a judgment dismissing for failure of proof its Lanham Act false advertising claims against a competitor, SmithKline Beecham Consumer Healthcare, L.P. (SmithKline). We affirm.

I.

The events leading to this litigation began in 1991 when Smith-Kline, concerned about a declining market for its principal douche product, hired a marketing consultant to devise ways to truly differentiate its product from competing brands and so improve its market position. As a result of this consultation, SmithKline planned two projects. First, it would re-design and seek to patent a new nozzle for its Massengill douche in order to make its copying more difficult. Then it would directly attack its principal competition, Fleet's Summer's Eve douche, by an advertising campaign designed to persuade consumers that Massengill douches cleansed better than did the Summer's Eve douche.

In 1995, after the douche nozzle had been redesigned by Human Factors, an ergonomics engineering firm, SmithKline began circulating with its product a freestanding advertising insert coupon which claimed that the Massengill douche was "Now Designed for Better Cleansing." No testing of the redesigned douche for specific cleansing properties preceded its marketing with the advertising insert.

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In preparation for its follow-up direct attack upon Fleet's Summer's Eve douche, SmithKline employed Product Investigation, an independent testing laboratory, to devise a means of testing the specific cleansing properties of douches. At the time, no such test generally recognized for its efficacy had been developed for use in the industry. Product Investigations came up with a testing procedure using a blue-dye marker which was then used in tests involving SmithKline's old-nozzle douche, its new-nozzle model, and the Summer's Eve douche. In quite general terms, the human-subject tests ultimately used involved a preparatory cleansing process, followed by the insertion of a blue-dye marker, after which the test douches were used and their relative efficacies in removing the marker-fluid measured. The ultimate test used employed as the specific cleansing agents the "extra cleansing vinegar and water" solutions used respectively in the Massengill (SmithKline) and Summer's Eve (Fleet) disposable douches. The results, as reported by the Product Investigations testers, showed that in terms of their relative efficacies in removing quantities of the test marker fluids, both the old and new Massengill douches outperformed the Summer's Eve douche, though the old Massengill outperformed the new-nozzle model.

Following completion of these tests, SmithKline ran a television advertisement claiming that "Massengill cleanses better than Summer's Eve." This was later withdrawn in conjunction with Smith-Kline's consent to withholding both advertising claims pending final decision in this litigation. Instead, SmithKline proposed to use the more specific advertising claim that "Massengill Extra Cleansing Vinegar and Water Douche Cleanses Better than Summer's Eve Extra Cleansing Vinegar and Water Douche."

Fleet then brought this action against SmithKline alleging violations of § 43(a) of the Lanham Act, 15 U.S.C.§ 1125(a), by the use of false advertising claims. 1 Specifically challenged were the earlier "Now Designed for Better Cleansing" ("improved design") claim and the later proposed "Massengill Extra Cleansing Vinegar and Water

¹ The action also included a state-law claim of product disparagement that was abandoned along the way, leaving only the Lanham Act claim for adjudication.

Douche Cleanses Better than Summer's Eve Extra Cleansing Vinegar and Water Douche" ("comparative superiority") claim.

The action was tried to the district court sitting with an advisory jury pursuant to Rule 39(c), Fed. R. Civ. P. The three-day trial that ensued was mainly devoted to the parties' conflicting expert opinion testimony and extensive documentary evidence respecting the claimed falsity of the two challenged claims.

Fleet's evidence consisted essentially of the testimony of two expert witnesses who, with supporting documentary evidence, challenged the scientific reliability of the blue-dye testing procedures upon which SmithKline concededly based its "comparative superiority" advertising claim, and the essential truth of the "improved design" claim.

Dr. Frank Dorsey, a statistician, made a number of criticisms of the blue-dye test methodology used by SmithKline's testers. On that basis, he questioned the reliability of the test results it produced.

Sarah Post, a Vice President and Director of Administration of Fleet, testified to the conduct by Fleet of two tests--a "bovine mucus" test and a "detergency study"--which, she opined, drew in question SmithKline's blue-dye test results. The detergency study, performed in 1985, consisted of dipping cloths stained in blood in douche solutions then in use by the two competitors. The bovine mucus test, from 1991, consisted of spinning bovine cervical mucus in douche solutions then in use by the competitors. Neither test used the vinegar and water solutions which were the subject of the "superior product" claim at issue.

As to the "improved design" claim, Fleet's witnesses pointed out that it was first made by SmithKline before any clinical tests were made of the Massengill douche's performance with the redesigned nozzle, and that the later blue-dye studies actually revealed that the later model did not cleanse as efficiently in terms of material removal as did the older model. This, they opined, indicated that the new Massengill douche was not, as claimed, "now designed for better cleansing."

SmithKline, in defense, presented the testimony of four expert witnesses: Dr. Morris Shelanski, who as director of Products Investigation, had developed and performed the blue-dye studies; Dr. Paul Starkey, SmithKline's Medical Director; Dr. Donald Pittaway, a gynecologist on the faculty of the Bowman Gray Medical Center; and Dr. James Leyden, a medical doctor on the faculty of the University of Pennsylvania School of Medicine. Both of the last two witnesses were paid consultants to SmithKline.

As to the "comparative superiority" claim, Dr. Shelanski, who developed and supervised conduct of the blue-dye studies, described the test methodology's design, purpose, and use, and gave as his opinion that the reported results showing that the Massengill douche cleansed better than did the Summer's Eve douche were scientifically reliable. His opinion was supported by those of Drs. Pittaway and Leyden based upon their studies of the test's methodology, conduct, and reported results. The test's reliability was also supported by the testimony of Dr. Starkey in refuting Dr. Dorsey's specific criticisms of the Shelanski methodology.

As to the "improved-design" claim, SmithKline witnesses described the new nozzle design, emphasizing those features that improved its mechanical performance over that of the old model. Specifically, they noted that it has deeper side channels which improved outflow, a more rounded tip which made insertion easier, and improved flow dynamics which made the douching process more gentle and, possibly, safer. As to its actual cleansing properties, as measured by the blue-dye studies, they conceded that it did not perform better than did the earlier design (as they had hoped it would) though, per those studies, it did still outperform the Summer's Eve douche in this respect.

Following conclusion of the evidence, the advisory jury returned a verdict in favor of Fleet, finding false both of the advertising claims. The district court, however, did not accept the verdict, as was its conceded prerogative, <u>see</u> 9 Charles Alan Wright & Arthur R. Miller, <u>Federal Practice and Procedure</u> § 2335 at 211-12 (2d ed. 1994), and, instead, found for SmithKline as to both of the advertising claims.

In a brief memorandum opinion, the court concluded that Fleet had failed to carry its burden to prove that either advertising claim was false in violation of § 43(a) of the Lanham Act.

As to the "comparative superiority" claim, the court expressly credited the expert opinions of SmithKline's witnesses over those of Fleet's expert as to the reliability of the blue-dye studies in demonstrating the superior cleansing efficacy of the Massengill douche. The court found "not only that the tests . . . were solid, even exceptional, clinical studies, but also that they clearly supported SmithKline's advertised claim."

As to the "improved design" claim, the court found, concentrating on evidence that the redesigned nozzle had mechanical features which "changed the flow dynamics . . . to make the douching process more gentle and effective," that the "now designed for better cleansing" claim had not been proven false.

Having found against Fleet on the merits, the court denied its claim that as "prevailing party" in an "exceptional case," it was entitled under 15 U.S.C. § 1117(a) (1997), to an award of attorney fees.

This appeal followed.

II.

The false advertising provision at issue, § 43(a) of the Lanham Act, 15 U.S.C. § 1125(a), provides in pertinent part:

Any person who, on or in connection with any goods or services . . . uses in commerce any word, term, name, symbol, or device, or any combination thereof, or any . . . false or misleading description of fact, or false or misleading representation of fact, which--

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(B) in commercial advertising or promotion, misrepresents the nature, characteristics, qualities, or

geographic origin of his or her or another person's goods, services, or commercial activities,

shall be liable in a civil action by any person who believes that he or she is or is likely to be damaged by such act.

15 U.S.C. § 1125(a)(1) (1997). Under this provision, both false advertising of a competitor's products and false advertising of one's own products are actionable. To constitute a violation of § 43(a), by either type of advertisement "the contested statement or representation must be either false on its face or, although literally true, likely to mislead and to confuse consumers given the merchandising context." Mylan Labs., Inc. v. Matkari, 7 F.3d 1130, 1138 (4th Cir. 1993), cert. denied, 510 U.S. 1197 (1994). If the advertising claim is literally false, "the court may enjoin the use of the claim without reference to the advertisement's impact on the buying public." McNeil-P.C.C., Inc. v. Bristol-Myers Squibb Co., 938 F.2d 1544, 1549 (2d Cir. 1991) (quotation omitted). Fleet's challenge to the advertising claims here in issue is of literal falsity. Whether an advertisement is literally false is an issue of fact. See L & F. Prods. v. Procter & Gamble Co., 45 F.3d 709, 712 (2d Cir. 1995).

Fleet challenges the district court's determinations of no literal falsity on the grounds that the court imposed upon Fleet a wrong-overly stringent--"burden of proof" on the issue, and, relatedly, that both of the ultimate fact findings were clearly erroneous.

We take these in turn.

A.

In addressing the "comparative superiority" claim, the district court announced that Fleet's burden was to prove affirmatively that the asserted fact of superior cleansing ability was literally false. In doing so, the court differentiated between advertising claims which in expressly or impliedly asserting a favorable fact about a product, further assert that it is based upon or supported by validating tests ("tests show" claims) and those that make no reference to validating tests but simply assert baldly a favorable fact about the advertiser's goods or

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services ("bald" claims).2 According to the court, when a "tests show" claim is challenged, the challenger must prove only that the referenced test did not validate the claim. When a "bald" claim is challenged, a "higher" burden is imposed to prove that the favorable fact asserted is itself false. The court then treated the "comparative superiority" claim as a "bald" claim to which the "higher" burden of proof applied and, presumably applying it, found the claim of superiority not proven to be literally false.

Fleet says that in applying this "higher" burden, the court committed prejudicial legal error requiring reversal as to the "comparative superiority" claim. Specifically, Fleet contends that, in the first place, the "comparative superiority" claim is not properly treated as a "bald" claim since it necessarily implied, though it did not expressly assert, validation by a comparative test. Next, it says that even if it were properly treated as a "bald" claim, the "burden of proof" as to such a claim is not properly considered to be a "higher" one, as the district court assumed. We disagree on the first point, and think the second misunderstands the district court's use of the term.

First off, we agree with the district court's basic point that, as several of our sister circuits have held, differentiation between the two types of claims may be required in order to determine what must be proven false and how that can be done. When an advertising claim of favorable fact either expressly or impliedly asserts that the fact is testor study-validated, the fact of the validation becomes an integral and critical part of the claim. Such a claim may therefore be proven literally false by showing only that the test asserted to validate it did not in fact do so. On the other hand, where the claim is made baldly, with no assertion of test or study validation, its literal falsity may only be proven by proof that the favorable fact baldly asserted is false. See, e.g., Rhone-Poulenc Rorer Pharms., Inc. v. Marion Merrill Dow, Inc., 93 F.3d 511, 514-15 (8th Cir. 1996) (recognizing different "standards" of proof for the two types of advertising claims); BASF Corp.

² The district court, employing other short-hand descriptives used by some courts to differentiate the two types, referred to the "tests show" type as "establishment," the "bald" typeas "non-establishment." See, e.g., BASF Corp. v. Old World Trading Co., Inc., 41 F.3d 1081, 1090 (7th Cir. 1994).

v. Old World Trading Co. Inc., 41 F.3d 1081, 1091 (7th Cir. 1994) (recognizing that proof required to prove literal falsity "will vary depending upon the statement made"--whether it does or does not make reference to validating tests); Castrol, Inc. v. Quaker State Corp., 977 F.2d 57, 62-63 (2d Cir. 1992) (holding that falsity of "tests show" claim may be proven by "showing that the tests... were not sufficiently reliable to permit one to conclude with reasonable certainty that they established the proposition"; falsity of "bald" claim may be proven only by evidence affirmatively showing its falsity).

While Fleet quibbles to some extent with whether the need and justification for this differentiation is settled in decisional law, we believe it is soundly based, and we take this opportunity to adopt it for use in this circuit. Fleet's principal contention is that even if applicable as a general rule, it was not properly applied here. The "comparative superiority" claim here, Fleet says, necessarily implied that it was validated by some clinical test; it was not therefore properly treated as a "bald claim" which could only be proven literally false by affirmative proof of its falsity. Here, instead, the argument goes, Fleet should only have been required to prove that the blue-dye tests which were revealed in litigation to be the basis of the claim "were not sufficiently reliable to permit [the conclusion] with reasonable certainty that they established the proposition." See Castrol, 977 F.2d at 62-63. We reject that contention.

First, we think that whether an advertising claim implicitly, though not expressly, asserts that it is test-validated must be considered a question of fact whose resolution is subject to clearly erroneous review. Here, the claim contained no express assertion of test validation nor is there any language in the text that implies it. We think the trial court need look no further in making this threshold determination, and we cannot declare its resulting finding of no implied test so

3 Though we adverted in Mylan Laboratories, 7 F.3d at 1137-38, to the differentiation principle as it had been applied in the Second Circuit, we did not have occasion there to apply it directly in reviewing a dismissal under Rule 12(b)(6), Fed. R. Civ. P. Mylan surely left open the possibility of eventual formal adoption of the principle by this court, and indeed has been cited by other courts as having already applied it. See Rhone-Poulenc, 93 F.3d at 514-15. We make its adoption express here.

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implausible as to be clearly erroneous. See Anderson v. City of Bessemer City, 470 U.S. 564, 575 (1985). The fact that it was later revealed in litigation that the claim was test-based does not alter this. The relevant question for determining the required proof is whether the advertisement made an assertion of test-validation to the consumer public. If it was not asserted in the advertised claim, it was not made part of the claim being challenged as false. If it is later revealed, through discovery or otherwise, that the claim was test-based, the claimant obviously may challenge the test's reliability in attempting to prove false the advertised fact, but falsity of that fact remains the required object of proof. So, we find no error in the district court's threshold determination that, because the "comparative superiority" claim was not a "tests show" type, Fleet's burden was to prove affirmatively that the advertised claim of "comparative superiority" was literally false.

As to the district court's characterization of the burden of proof in "bald" claim cases as being "higher" than that in "tests show" cases, we understand the court not to have intended "higher" in the sense of "greater than the normal preponderance-of-evidence civil burden." We take the court to have meant only that proving the falsity of a fact asserted in an advertising claim may well be more difficult than merely proving that a test asserted to validate the claim is not sufficiently reliable to do so. So understood, the court did not legally err in imposing the former burden upon Fleet here.

B.

In addition to this burden of proof contention respecting the "comparative superiority" claim, Fleet contends that the district court's ultimate finding that the claim was not false is clearly erroneous. Two specific grounds are urged. First, and simply, that the finding is against the overwhelming weight of the evidence. Relatedly, that it was based upon evidence respecting the blue-dye tests which "fail[s] to meet the requirements for scientific evidence" established in Daubert v. Merrell Dow Pharmaceuticals, Inc., 509 U.S. 579 (1993). Neither ground has merit.

Our standard of review of district court fact findings is greatly deferential under controlling authority.

If the district court's account of the evidence is plausible in light of the record viewed in its entirety, the court of appeals may not reverse it even though convinced that had it been sitting as the trier of fact, it would have weighed the evidence differently. Where there are two permissible views of the evidence, the factfinder's choice between them cannot be clearly erroneous.

Anderson, 470 U.S. at 573-74. Deference may be at its peak where the dispositive findings are based upon credibility choices between conflicting testimony of witnesses each of whom gives "a coherent and facially plausible story that is not contradicted by extrinsic evidence"; in such cases, such findings "if not internally inconsistent, can virtually never be clear error." <u>Id.</u> at 575. And this court has emphasized that we "should be especially reluctant to set aside a finding based on the trial court's evaluation of conflicting expert testimony." <u>Hendricks v. Central Reserve Life Ins. Co.</u>, 39 F.3d 507, 513 (4th Cir. 1994).

Here, the three-day trial to the court was devoted in the main to expert opinion evidence respecting the scientific reliability of the blue-dve test upon which the "comparative superiority" claim concededly was based. As went that test, so went the truth or falsity of the claim asserted on its basis. For SmithKline, four expert witnesses described the test and opined that it and the results it produced were scientifically valid. For Fleet, one expert opined directly in opposition to those opinions that there were flaws in the test methodology that drew in question, indeed undercut, its reliability. Another expert described tests done by Fleet which she opined achieved results that contradicted those obtained by the blue-dye tests. The district court found on this evidence that SmithKline's experts were well qualified by training and experience to testify on douche cleansing and products. The court stated: "This testimony and evidence indicated not only that the tests used by SmithKline were solid, even exceptional clinical studies, but also that they clearly supported SmithKline's advertised claim." (JA 14.) In so finding, the court necessarily chose to credit those witnesses' accounts over any conflicting opinions advanced by Fleet's experts.

We have studied the opposing testimony, including the critical opposing opinions as to the reliability of the studies. The most that

possibly could be said in support of Fleet's position is that its experts' opinions are equally as coherent and plausible as are those of Smith-Kline's experts, and that neither is "contradicted by extrinsic evidence." In such circumstances, we cannot declare clearly erroneous the district court's acceptance of one and rejection of the other of two equally "permissible views of the evidence." Anderson, 470 U.S. at 574-75.

Fleet's Daubert contention is also unavailing. As SmithKline points out, Fleet made no Daubert objection to admission of the extensive testimony of SmithKline's expert witnesses about the bluedye tests' methodology, conduct, and results. Fleet counters that it need not have: that its challenge here is not to the admissibility of this evidence but to its insufficiency when tested by Daubert principles to support the district court's finding of the tests' scientific reliability. That cannot be right. Daubert deals with the admissibility of this kind of "scientific" evidence. See Daubert, 509 U.S. at 582, 585 (so identifying dispositive issue). As with all rules governing admissibility, its application to particular evidence is to be raised and resolved in the trial court. See id. at 592-97 (outlining"gatekeeper" role of trial court in applying rule). There the proponent can attempt upon objection to lay the proper foundation for admitting the evidence and the objector can challenge its sufficiency. See id. In this way the question of admissibility can be fairly resolved as a threshold matter. Fleet essentially would have this court engage in a first instance application of <u>Daubert</u> principles on a record completely inadequate for the purpose. This cannot be done under the guise of a challenge to the substantive sufficiency of this evidence.

C.

Fleet challenges the district court's finding that the "improved design" claim was not literally false on the sole ground that the finding is clearly erroneous. 4 We disagree.

4 Though Fleet indicates awareness that non-comparative advertising claims as well as comparative claims may involve express or implicit assertions of test-validation, it makes no contention that the non-comparative "improved design" claim here implied test-validation thereby invoking the "tests show" proof requirement. (See Appellant's Br. 32-35.)

The issue here boils down to whether in considering SmithKline's advertised claim that its Massengill douche was"Now Designed for Better Cleansing," "better cleansing" should be considered to pertain only to its specific cleansing function--material evacuation--or should be considered to describe the total douching process.

Fleet contends that, viewed from the consumer public's viewpoint, it should be confined to the specific cleansing function, to how well it performed the critical evacuation function. So confined, Fleet points out, SmithKline's own blue-dye tests inarguably demonstrate the claim's literal falsity, hence clear error in the district court's finding of no falsity. For, as SmithKline concedes, those tests showed that the new-nozzle douche did not perform the core material evacuation function as well as did its old-nozzle douche.

To the contrary, SmithKline contends, and the district court accepted the proposition, that "designed for better cleansing" should be considered to pertain to the total douching process. So considered, its truth as advertisement must be assessed in light of evidence demonstrating other, mechanical, improvements in the new nozzle design which made the douching process gentler and, possibly, safer to the user. On this aspect of the new design, there was, again, conflicting opinion evidence. SmithKline's witnesses extolled the virtues of friendlier consumer use, as consumers would view the matter, brought about by the improved mechanical design features. Fleet's witnesses, in opposition, downplayed the claimed beneficial effects.

Here again, confronted with conflicting opinion evidence on these fact issues--how the consumer public would understand the claim and whether the new design did make for better cleansing if the terms were broadly understood--the district court chose to credit the testimony of SmithKline's witnesses over that of Fleet's. Here again, reviewing that finding, we cannot declare clearly erroneous the district court's choice between at least equally plausible conflicting opinions on these fact issues.

D

Because we affirm the district court's decision rejecting on the merits both of Fleet's claims of false advertising, we also affirm the court's denial of Fleet's claim for attorney fees.

AFFIRMED